Subpart C [Reserved]

Subpart D—Standards of Identity [Reserved]

PART 106—INFANT FORMULA QUALITY CONTROL PROCEDURES

Subpart A—General Provisions

Sec.
106.1 Status and applicability of the quality control procedures regulation.
106.3 Definitions.

Subpart B—Quality Control Procedures for Assuring Nutrient Content of Infant Formulas

106.20 Ingredient control.
106.25 In-process control.
106.30 Finished product evaluation.
106.90 Coding.

Subpart C—Records and Reports

106.100 Records.

Subpart D—Notification Requirements

106.120 New formulations and reformulations.

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Subpart A—General Provisions

§ 106.1 Status and applicability of the quality control procedures regulation.

(a) The criteria set forth in §§106.20, 106.25, 106.30, 106.90, and 106.100 shall apply in determining whether an infant formula meets the safety, quality, and nutrient requirements of section 412 of the act and the requirements of regulations promulgated under section 412(a)(2) of the act.

(b) The failure to comply with any regulation set forth in §§106.20, 106.25, 106.30, 106.90, and 106.100 applicable to the manufacturing, processing, and packaging of an infant formula shall render such formula adulterated under section 412(a)(1)(C) of the act.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 106.3 Definitions.

The definitions and interpretations contained in section 201 of the act are applicable to such terms when used in this part. The following definitions shall also apply:

(a) *Indicator nutrient.* An indicator nutrient is a nutrient whose concentration is measured during the manufacture of an infant formula to confirm complete addition and/or uniform distribution of a premix or other substance of which the indicator nutrient is a part.

(b) *In-process batch.* An in-process batch is a combination of ingredients at any point in the manufacturing process before packaging.

(c) *Manufacturer.* A manufacturer is a person who prepares, reconstitutes, or otherwise changes the physical or chemical characteristics of an infant formula and/or packages the product in a container for distribution.

(d) *Nutrient.* A nutrient is any vitamin, mineral, or other substance required in accordance with the table set out in section 412(g) of the act or by regulations promulgated under section 412(a)(2)(A) of the act.

(e) *Nutrient premix.* A nutrient premix is a combination of ingredients containing two or more nutrients. A nutrient premix either may be received from a supplier or be prepared by an infant formula manufacturer.

Subpart B—Quality Control Procedures for Assuring Nutrient Content of Infant Formulas

§ 106.20 Ingredient control.

(a) Except as provided in §106.20(b), no analysis before use in manufacturing is needed for ingredients that are generally stable in shipping and storage, and that either are received under a supplier's guarantee or certification that the mixture has been analyzed as to nutrient composition or are labeled as having nutrient compositions complying with specifications in the U.S. Pharmacopeia, the National Formulary, the Food Chemicals Codex, or other similar recognized standards.

(b) Unless each batch of finished product is analyzed as specified in §106.30(b)(1) before release of product

for commercial or charitable distribution, the following shall apply:

(1) When an ingredient is relied upon as a source of a nutrient(s) and when evidence indicates that such nutrient(s) in that ingredient is likely to be affected adversely by shipping or storage conditions, the manufacturer shall analyze that ingredient for each relied-upon nutrient that may be affected, using validated analytical methods.

(2) Ingredients, including nutrient premixes, that are either without a supplier's guarantee or certification, or not labeled as complying with prescribed standards, shall be sampled and analyzed for each relied-upon nutrient by the manufacturer, except that ingredients used as a major source of protein or fat need not be analyzed for each relied-upon nutrient if the manufacturer has records to show that each relied-upon nutrient is present at a reasonably constant level. Nutrient premixes prepared by the infant formula manufacturer shall be sampled and analyzed for each relied-upon nutrient. Nutrient premixes which are received from suppliers shall be sampled and analyzed for each relied-upon nutrient unless the supplier has sampled and analyzed each batch of premix for each relied-upon nutrient and has so certified in writing.

§ 106.25 In-process control.

(a) For each infant formula, a master manufacturing order shall be prepared and approved by a responsible official of the manufacturer. The manufacturer shall establish a quality control system that assures and verifies the addition of each ingredient specified in the manufacturing order.

(b) Unless each batch of finished product is analyzed as specified in § 106.30(b)(1), the manufacturer shall analyze each in-process batch for:

(1) Solids;

(2) Protein, fat, and carbohydrates (carbohydrates either by analysis or by mathematical difference);

(3) The indicator nutrient(s) in each nutrient premix;

(4) Each nutrient added independently of nutrient premixes during formulation of the product, except for linoleic acid, vitamin D, vitamin K, choline, inositol, and biotin; and

(5) Solids or an appropriate nutrient to confirm proper dilution when final dilution is made after performance of the analyses in paragraph (b) (1) through (4) of this section.

§ 106.30 Finished product evaluation.

(a) The manufacturer shall establish criteria for sampling and testing to ensure that each batch of infant formula meets the nutrient requirements of section 412(g) of the act or of regulations promulgated under section 412(a)(2) of the act before release of product for commercial or charitable distribution.

(b)(1) *Immediate analysis.* Before release of product for commercial or charitable distribution, the manufacturer shall analyze representative samples of each batch of finished product for:

(i) Specific nutrient(s) to assess process degradation; and

(ii) All nutrients not previously analyzed for by the manufacturers, unless each in-process batch is analyzed for nutrients as specified in § 106.25(b) and the ingredients are analyzed as specified in § 106.20(b). No analyses are needed for linoleic acid, vitamin D, vitamin K, choline, inositol, and biotin; and for nutrients that are added as a part of a nutrient premix analyzed by the manufacturer or having a supplier's guarantee or certification and for which an indicator nutrient(s) was analyzed by the manufacturer.

(2) *Periodic analysis.* The manufacturer shall sample at least one newly processed finished product batch every 3 months and shall analyze representative samples for all nutrients except those that the manufacturers measured in the immediate analysis of that product batch.

(3) *Stability analysis.* Using representative samples collected from finished product batches, the manufacturer shall conduct stability analysis for selected nutrients with sufficient frequency to substantiate the maintenance of nutrient content throughout the shelf life of the product.

(c) The manufacturer shall evaluate new formulations and the effect of changes in ingredients or processing conditions that could affect the level of